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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,773	01/16/2004	Seng H. Cheng	07680.0018	6298

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,773

Applicant(s)

CHENG ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, 13-18, 20 and 21, drawn to a method of treating a subject having a lysosomal disease, such as Fabry disease, comprising administering a gene therapy vector and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase, classified in class 514, subclasses 44 and 2.
 - II. Claims 1, 3, 4, 7-9 and 13-21, drawn to a method of treating a subject having a lysosomal disease, such as Fabry disease, comprising administering a gene therapy vector and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclasses 44 and 1.
 - III. Claims 1-9 and 13-21, drawn to a method of treating a subject having a lysosomal disease, such as Fabry disease, comprising administering a gene therapy vector, an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase, and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclasses 44, 2 and 1.
 - IV. Claims 1-6, 10-18 and 22, drawn to a method of treating a subject having a lysosomal disease, such as Pompe disease, comprising administering a gene therapy vector and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase, classified in class 514, subclasses 44 and 2.
 - V. Claims 1-6, 10-19 and 22, drawn to a method of treating a subject having a lysosomal disease, such as Pompe disease, comprising administering a gene

- therapy vector and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclasses 44 and 1.
- VI. Claims 1-6, 10-19 and 22, drawn to a method of treating a subject having a lysosomal disease, such as Pompe disease, comprising administering a gene therapy vector, an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase, and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclasses 44, 2 and 1.
- VII. Claims 23, 24, 26-32 and 34, drawn to a composition for treating a lysosomal storage disease, such as Fabry disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-galactosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase, classified in class 514, subclasses 44 and 2.
- VIII. Claims 23, 24, 26, 27 and 29-34, drawn to a composition for treating a lysosomal storage disease, such as Fabry disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-galactosidase, under the control of a tissue specific regulatory element and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclass 44 and 1.
- IX. Claims 23, 24 and 26-34, drawn to a composition for treating a lysosomal storage disease, such as Fabry disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-galactosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant

lysosomal hydrolase, such as alpha-galactosidase, and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclasses 44, 2 and 1.

- X. Claims 23, 25-32 and 35, drawn to a composition for treating a lysosomal storage disease, such as Pompe disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-glucosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase, classified in class 514, subclasses 44 and 2.
- XI. Claims 23, 25-27, 29-33 and 35, drawn to a composition for treating a lysosomal storage disease, such as Pompe disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-glucosidase, under the control of a tissue specific regulatory element and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclass 44 and 1.
- XII. Claims 23, 25-33 and 35, drawn to a composition for treating a lysosomal storage disease, such as Pompe disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-glucosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase, and a small molecule capable of treating a lysosomal storage disease, classified in class 514, subclasses 44, 2 and 1.

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Claims 1, 3, 4, 13-18, 20 and 21 link(s) inventions I-VI. Claims 7-9 link(s) inventions I-III. Claims 2, 5 and 6 link(s) inventions I and III-VI. Claim 19 link(s) inventions II-III, V and VI. Claims 20 and 21 link(s) inventions I-III. Claims 10-12 and 22 link(s) inventions IV-VI. Claims 23, 26, 27 and 29-32 link(s) inventions VII-XII. Claims 24 and 34 link(s) inventions VII-IX. Claims 25 and 35 link(s) inventions X-XII. Claim 28 link(s) inventions VII, IX, X and XII. Claim 33 link(s) inventions VIII-IX and XI-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 27-30.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are distinct from each other because they are drawn to materially different methods having different compositions that differ in chemical structures, physical properties and biological functions: a protein, a small molecule, and a protein + a small molecule. A combination of a protein and a small molecule is different from just protein or small molecule alone. The functions of the protein and the small molecule could have synergistic effect or could antagonize each other. They are drawn to different methods that differ at least in method steps, reagents used, dosages and schedules used, response variables, and criteria of success. There is

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serious burden to search all of groups I-III. They have different classifications and require separate searches. Thus, groups I-III are not obvious variants and are patentably distinct.

Similarly, groups IV-VI are patentably distinct from each other for the same reason.

Groups VII-IX are distinct from each other because they are drawn to different compositions having different chemical structures, physical properties, and biological functions: a protein, a small molecule, and a protein + a small molecule. A combination of a protein and a small molecule is different from just protein or small molecule alone. The functions of the protein and the small molecule could have synergistic effect or could antagonize each other. There is serious burden to search all of groups VII-IX. They have different classifications and require separate searches. Thus, groups VII-IX are not obvious variants and are patentably distinct. Similarly, groups X-XII are patentably distinct from each other for the same reason.

Groups I-III and groups IV-VI are distinct from each other because they are drawn to different scientific considerations: a method for treating a lysosomal disease, such as a Fabry disease by using alpha-galactosidase vs. a method for treating a lysosomal disease, such as a Pompe disease by using alpha-glucosidase. They are materially different methods that differ in objectives, method steps, reagents used, dosages and schedules used, response variables, and criteria of success. There is serious burden to search all these groups and require separate search. Thus, groups I-III and groups IV-VI are not obvious variants and are patentably distinct.

Groups VII-IX and groups X-XII are distinct from each other because they are drawn to different scientific considerations: a composition for treating a lysosomal disease, such as a Fabry disease by using alpha-galactosidase vs. a composition for treating a lysosomal disease, such as a Pompe disease by using alpha-glucosidase. They differ in objectives, reagents used,

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dosages and schedules used, response variables, and criteria of success. There is serious burden to search all these groups and require separate search. Thus, groups VII-IX and groups X-XII are not obvious variants and are patentably distinct.

Invention VII-IX and inventions I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene therapy vector can be used as a probe or can be used to produce a recombinant protein instead of treating a disease. The protein can be used to produce antibody or for antibody purification. The small molecule can be used as a testing agent or for the synthesis of other agents instead of treating a disease. Thus, inventions VII-IX and inventions I-III are patentably distinct from each other. Similarly, inventions X-XII and inventions IV-VI are patentably distinct from each other for the same reasons.

Groups VII-IX are unrelated to groups IV-VI because the product of groups VII-IX is not used or otherwise involved in the process of groups IV-VI. Thus, groups VII-IX are patentably distinct from groups IV-VI.

Groups X-XII are unrelated to groups I-III because the product of groups X-XII is not used or otherwise involved in the process of groups I-III. Thus, groups X-XII are patentably distinct from groups I-III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'SL Chen', written in a cursive style.

**SHIN-LIN CHEN
PRIMARY EXAMINER**